REMARKS

The Official Action dated August 14, 2003 has been carefully considered. Additionally, Applicants acknowledge with appreciation the telephone interview which the Examiner courteously afforded Applicants' undersigned representative on November 20, 2003. As discussed during the interview, it is believed that all of claims 4, 5, 7-11 and 18-23 are allowable. Accordingly, reconsideration is respectfully requested.

In the Official Action, the Examiner indicated that claims 22 and 23 are allowable. As discussed during the interview, claims 7-11 and 18-21 depend directly or indirectly from claim 22. Thus, these claims are also prima facie allowable. Reconsideration is respectfully requested.

Claim 4 was rejected under 35 U.S.C. §102(b) as being anticipated by Chemical Abstract 87:63008. The Examiner asserted that the chemical abstract teaches use of the claimed prostaglandin in a pharmaceutical formulation as a bronchodilator.

However, Applicants submit that the composition of claim 4 is not anticipated by and is patentably distinguishable from the teachings of the cited chemical abstract. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, the cited chemical abstract discloses the synthesis and bronchodilator activity of DL-16,16-trimethylene prostaglandins. On the other hand, claim 4 is directed to a composition for the treatment of glaucoma and ocular hypertension. The composition comprises a therapeutically active and physiologically acceptable amount of 15(R,S)-16,16-trimethylene PGE_2, or an alkyl ester thereof, or a pharmaceutically acceptable salt thereof, and an ophthalmologically-compatible vehicle. Additionally, the composition is adapted for topical application to the eye. Applicants find no teaching or suggestion in the cited chemical abstract relating to a composition containing a prostaglandin in combination

with an ophthalmologically-compatible vehicle, or relating to a composition adapted for topical application to the eye.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of the cited chemical abstract to teach the combination of a prostaglandin as presently claimed and an ophthalmologically-compatible vehicle, and the failure of the cited chemical abstract to teach a composition adapted for topical application to the eye, the cited chemical abstract fails to disclose each and every element set forth in claim 4. Thus, the chemical abstract does not anticipate claim 4 under 35 U.S.C. §102.

In the Official Action, the Examiner asserted that Applicants have alleged criticality to the different use of the claimed composition, rather than a difference in the composition. However, as discussed during the interview, the composition defined by claim 4 comprises not only the recited PGE_2 compound, but also an ophthalmologically-compatible vehicle. Additionally, the composition is adapted for topical application to the eye. In contrast, the cited chemical abstract provides no teaching relating to an ophthalmologically-compatible vehicle, or a composition adapted for topical application to the eye. One skilled in the art will recognize that the disclosure of a particular compound does not inherently disclose a composition adapted for topical application to the eye, or the compound in combination with an ophthalmologically-compatible vehicle. Thus, Applicants are not relying on an intended use of the composition of claim 4 to distinguish over the cited chemical abstract, but rather of the components and properties of the claimed composition. It is therefore submitted that the composition of claim 4 is not anticipated by the cited chemical abstract under 35 U.S.C. §102, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 5-11 and 18-21 were rejected under 35 U.S.C. §102(b) as being anticipated by the Stjernschantz et al U.S. Patent No. 5,296,504. The Examiner asserted that Stjernschantz et al teach the use of the claimed prostaglandins in a pharmaceutical formulation for the treatment of glaucoma.

As noted above, claims 7-11 and 18-21 directly or indirectly depend from allowed claim 22. Additionally, claim 6 is cancelled. It is therefore believed that the present rejection relates only to present claim 5. However, Applicants submit that the composition defined by claim 5 is not anticipated by and is patentably distinguishable from the teachings of Stjernschantz et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, claim 5 is directed to a composition for the treatment of glaucoma and ocular hypertension. The composition comprises a therapeutically effective and physiologically acceptable amount of a prostaglandin analog which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof, and an ophthalmologically-compatible vehicle. The prostaglandin analog is 13,14-dihydro-17-(3-fluorophenyl)-18,19,20-trinor-PGE_2 or an alkyl ester thereof. The composition is adapted for topical application to the eye. As noted in the present specification and as discussed with the Examiner during the interview, Applicants have discovered that the compound of claim 5 is an EP_1 selective agonist and therefore are advantageous for reducing intraocular pressure with significantly reduced melanogenesis as a side effect (see, for example, the specification at page 5, second and third paragraphs).

Stjernschantz et al disclose prostaglandin derivatives for the treatment of glaucoma or ocular hypertension. Derivatives of PGA, PGB, PGD, PGE and PGF, in which the omega chain contains a ring structure, are disclosed. Numerous compounds are covered by the

generic formula which Stjernschantz et al disclose. However, Applicants find no specific teaching by Stjernschantz et al relating to the prostaglandin analogue included in the composition of claim 5, namely 13,14-dihydro-17-(3-fluorophenyl)-18,19,20-trinor-PGE_2 or an alkyl ester thereof. Additionally, Applicants find no teaching by Stjernschantz et al relating to prostaglandin analogues which are selective agonists for EP_1 prostanoid receptors. In fact, Applicants advise that compounds similar to that of claim 5, for example 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF_2 alpha (omitting the 3-fluoro substituent on the phenyl group), which is the free acid of latanoprost, the active ingredient of Xalatan is a prostaglan FP receptor agonist (see, for example, the attached Stjernschantz et al, *Drugs of the Future*, 17(8):691-704 (1992), particularly page 699), as is 16-phenoxy(3-trifluoromethyl)-17,18,19,20-tetranor-PGF_2 alpha (having a fluoro group but in combination with other different substituents), which is the free acid of travapost, the active ingredient of Travatan.

Thus, not only is the prostaglin analogue in the composition of claim 5 not specifically disclosed by Stjernschantz et al, Applicants have discovered that it exhibits a selective agonist property different from similar compounds specifically disclosed by Stjernschantz et al. In view of the failure of Stjernschantz et al to specifically teach the prostaglandin analog included in the composition of claim 5, and to recognize the selective agonist for EP_1 prostanoid receptor activity exhibited thereby, Stjernschantz et al do not disclose each and every element of claim 5. Thus, Stjernschantz et al do not anticipate claim 5 under 35 U.S.C. §102, *In re Robinson, supra*. It is therefore submitted that the rejection has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the r jections under 35 U.S.C. §102 and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

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